



Nam-Du KIM, et al.  
Appln. No. 10/531,299  
Amendment and Request for Reconsideration

### **REMARKS**

Claims 1-6 are all the claims pending in the application. Claim 1 has been amended to more clearly define the subject matter of the present invention. Support for the amendment may be found at, for example, page 7, lines 11-14. No new matter has been introduced and entry of the amendment is respectfully requested.

#### **I. Information Disclosure Statement**

The Office Action has indicated that a proper Information Disclosure Statement which identifies the references discussed in the specification at, for example, page 3, line 8, page 4, line 7, and page 6, line 14, has not been filed. The specification refers to U.S. Patent No. 4,804,663, WO 01/85731, Korean Patent Publication No. 96-9435, Spanish Patent Publication No. 2050069, Spanish Patent Publication No. 2074966, U.S. Patent No. 4,485,107 and U.S. Patent No. 4,804,663. Applicants would like to draw the Examiner's attention to the Information Disclosure Statements filed on April 14 and July 19, 2005. Copies of WO 01/85731 and Korean Patent Publication No. 96-9435 were submitted as an Information Disclosure Statement on April 14, 2005, along with EP 0196132 and WO 0212200. U.S. Patent No. 4,804,663, Korean Patent Publication No. 96-9435 and Spanish Patent Publication No. 2074966 were listed in an Information Disclosure Statement submitted on July 19, 2005, along with copies of each publication except US patent publication. It is noted that Applicants have received the initialed PTO/SB/08 A & B forms, which identified these references.

Nam-Du KIM, *et al.*  
Appln. No. 10/531,299  
Amendment and Request for Reconsideration

Applicants note that U.S. Patent No. 4,485,107 is not listed in any of the IDSs submitted in the present application. Therefore, Applicants submit an Information Disclosure Statement under a separate letter.

## **II. Claim Rejections – 35 U.S.C. § 112**

Claims 1 to 6 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement because the claims contain subject matter which was not described in the specification; and also under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Office Action asserts that the claims of the application fail to define the basis for the percentage determination of the aqueous alkali hydroxide. Claim 1 has been amended to clarify the basis of the concentration of alkali hydroxide in an aqueous alkali hydroxide solution.

The Office Action states “Reiter, et al., International Pub. No. WO 03/042212, published May 22, 2003 [Reiter], serves as evidence (page 9, line 15 - page 10, line 4, *inter alia*) that by reacting the hydrochloride salt of the oxime of Reiter’s Formula II with a haloethylpyrimidine of Reiter’s Formula XIV in the present of a base at reflux, Reiter did not obtain risperidone, but an oxime intermediate (Reiter’s Formula II, page 7, line 3+).” However, Reiter does not disclose a reaction of a compound of Formula (II) with a compound of Formula (XIV). To the extent, Reiter discloses a reaction of a compound of Formula (XIV) and a piperidine oxime derivative of

Nam-Du KIM, *et al.*  
Appln. No. 10/531,299  
Amendment and Request for Reconsideration

Formula V in *the presence of a base*, the reaction produces an oxime of Formula (II), which sequentially is subjected to ring-closure in *C<sub>1-4</sub>-alkanol* (an inert organic solvent) containing alkali hydroxide. Page 9, line 5 - page 10, line 4. Therefore, the reaction parameters of Reiter differs from those of the presently claimed invention, and thus, the resulting products are not necessarily the same.

The Office Action asserts that the phrase “comprises” of Claim 1 of the present application leaves it open to the additional presence of the organic and inorganic bases specified by Reiter et al., Int. Pub. No. WO 03/042212. Applicants do not agree. Furthermore, Reiter, as discussed above, uses *C<sub>1-4</sub>-alkanol* (an inert organic solvent) containing alkali hydroxide, not an aqueous alkali hydroxide solution.

Accordingly, it is believed that the rejections under 35 U.S.C. § 112 are not sustainable and it is respectfully requested that the rejections be withdrawn.

### **III. Claim Rejections – 35 U.S.C. § 102 & § 103**

Claims 1 to 6 stand rejected under 35 U.S.C. § 102(e) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Reiter.

Reiter has an international filing date (which can be considered as US filing date) of November 13, 2002, which is later than the invention date (here, the earliest priority filing date which is October 18, 2002) of the present application. Applicants note that the Office Action has acknowledged a receipt of the priority document. Applicants submit herewith a full English

Nam-Du KIM, *et al.*  
Appln. No. 10/531,299  
Amendment and Request for Reconsideration

translation of Korean Patent Application No. 10-2002-0063696. The English translation shows the priority document describes the presently claimed invention.

Accordingly, the rejections under 35 U.S.C. §§ 102(e) and/or 103(a) are not sustainable and it is respectfully requested that the rejections be withdrawn.

#### IV. Conclusion

In view of the foregoing amendments and discussions, it is respectfully submitted that the present invention as defined in the pending Claims 1 to 6 is in full compliance with all the statutory requirements, and, therefore, it is earnestly requested that the Examiner's rejections be withdrawn and that the pending claims be allowed in their present form.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Sunhee Lee  
Registration No. 53,892

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE  
**23373**  
CUSTOMER NUMBER

Date: October 26, 2006

Attachment : Sworn English translation of priority document  
(KR 10-2002-0063696) 8